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10/552,460	10/07/2005	Alberto Sardo	P09911US00/BAS	2270
881 7590 07/01/2011 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900			EXAMINER	
			GWARTNEY, ELIZABETH A	
ALEXANDRIA	A, VA 22314		ART UNIT	PAPER NUMBER
			1781	
			NOTIFICATION DATE	DELIVERY MODE
			07/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)	
	10/552,460	SARDO, ALBERTO	
Office Action Summary	Examiner	Art Unit	
	ELIZABETH GWARTNEY	1781	
The MAILING DATE of this communication a Period for Reply	appears on the cover sheet wit	h the correspondence address	
A SHORTENED STATUTORY PERIOD FOR REI WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the material patent term adjustment. See 37 CFR 1.704(b).	A DATE OF THIS COMMUNIC R 1.136(a). In no event, however, may a reprised will apply and will expire SIX (6) MONT atute, cause the application to become ABA	ATION. Oly be timely filed HS from the mailing date of this communication. NDONED (35 U.S.C. § 133).	
Status			
1) ■ Responsive to communication(s) filed on 1: 2a) ■ This action is FINAL . 2b) ■ T 3) ■ Since this application is in condition for allow closed in accordance with the practice under	his action is non-final. wance except for formal matte	rs, prosecution as to the merits is	
Disposition of Claims			
4) ☑ Claim(s) 39-43,47,54 and 56-76 is/are pend 4a) Of the above claim(s) is/are without 5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) 39-43,47,54 and 56-76 is/are reject 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and	drawn from consideration.		
Application Papers			
9) The specification is objected to by the Exam 10) The drawing(s) filed on is/are: a) a Applicant may not request that any objection to t Replacement drawing sheet(s) including the cort 11) The oath or declaration is objected to by the	accepted or b) \square objected to be the drawing(s) be held in abeyand rection is required if the drawing(s	e. See 37 CFR 1.85(a).) is objected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the p application from the International Bur * See the attached detailed Office action for a line	ents have been received. ents have been received in Appriority documents have been reau (PCT Rule 17.2(a)).	plication No eceived in this National Stage	
Attachment(s)	»□	(DTO 440)	
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 	Paper No(s)	mmary (PTO-413) /Mail Date ormal Patent Application _·	

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DETAILED ACTION

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 11, 2011 and supplemental response filed on April 7, 2011 have been entered.
- 2. Claims 39-43, 47, 48, 54 and 56-76 are pending.
- 3. The previous rejections under 35 U.S.C. §112 1st and 2nd paragraphs have been withdrawn in light of Applicant's amendment filed April 7, 2011.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 65, 72, 73 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia-Mina et al. (EP 1 106 070 A2).

Regarding claims 65, 72, 73 and 76, Garcia-Mina et al. disclose a method for treating fruits and vegetables comprising bathing the fruits and vegetables at a temperature of 45° to 50°C in a composition comprising lecithin and a fundamental active ingredient, eugenol (Abstract, [0019], [0032]). Garcia-Mina et al. also disclose an aqueous solution comprising lecithin (i.e. composition including water-[0035]/Formula 1, [0042]/Formula 2) and diluting the solution prior to bathing fruits and vegetables (*see* in a bath , diluted, concentration: 200-1000 ppm - [0032], claims 4-5). Specifically, Garcia-Mina et al. also disclose a composition that comprises 15% eugenol, 20% surface-active complex (i.e. lecithin - [0019]), and 25% water ([0035]). Garcia-Mina et al. also disclose that the composition dose is between 1 and 10000 ppm ([0019]/L13).

While there is no explicit disclosure regarding the amount of lecithin, given that Garcia-Mina disclose the equivalence and interchangeability of using lecithin with using Twen 80 ([0019]), it would have been obvious to one of ordinary skill in the art to also use lecithin in Application/Control Number: 10/552,460

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amount of between 0.1 and 3300 ppm (given product is treated in a solution of 1 to 10000 ppm concentration wherein 10-30% of the solution comprises lecithin - claims 3-4).

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While it is recognized that the phrase "consisting essentially of" narrows the scope of the claims to the specified ingredients and those which do not materially affect the basic and novel characteristics of the claimed invention, absent a clear indication of what the basic and novel characteristics are, "consisting essentially of" is construed as equivalent to "comprising".

Further, the burden is on the applicant to show that the additional ingredients in the prior art, would in fact be excluded from the claims and that such ingredients would materially change the characteristics of the applicant's invention, See MPEP 2111.03.

8. Claims 39-43, 47-48, 54, 56-64, 66-71, 74 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia-Mina et al. (EP 1 106 070 A2) in view of Schur (US 6,514,551).

Regarding claims **39**, **74** and **75**, Garcia-Mina et al. disclose a method for controlling post-harvest pathology of fruits and vegetables (i.e. affliction of pathogenic agents and processes of chemical degeneration of the skin) comprising applying a composition containing a fundamental active ingredient, eugenol, and a surface active including lecithin (Abstract, [0001], [0016], and [[0019]). Garcia-Mina et al. disclose a composition wherein the surface active is in an aqueous solution (i.e. composition including water-[0035]/Formula 1, [0042]/Formula 2) and diluted (*see* in a bath, diluted, concentration: 200-1000 ppm - [0032], claims 4-5). Specifically, Garcia-Mina et al. also disclose a composition that comprises 15% eugenol, 20% surface-active

complex (i.e. lecithin - [0019]), and 25% water ([0035]). Garcia-Mina et al. also disclose that the composition dose is between 1 and 10000 ppm ([0019]/L13).

While it is recognized that the phrase "consisting essentially of" narrows the scope of the claims to the specified ingredients and those which do not materially affect the basic and novel characteristics of the claimed invention, absent a clear indication of what the basic and novel characteristics are, "consisting essentially of" is construed as equivalent to "comprising". Further, the burden is on the applicant to show that the additional ingredients in the prior art, would in fact be excluded from the claims and that such ingredients would materially change the characteristics of the applicant's invention, See MPEP 2111.03.

Further, Garcia-Mina et al. disclose a composition comprising between 10% and 30% surface active compound (see preparation of 1 kg. product – [0031], claim 3) that is known under the tradename Twen 80 and or Span 80). While there is no explicit disclosure regarding the amount of lecithin, given that Garcia-Mina disclose the equivalence and interchangeability of using lecithin with using Twen 80 ([0019]), since Garcia-Mina disclose a composition comprising between 10% and 30% surface active (see preparation of 1 kg. product – [0031], claim 3) that is known under the tradename Twen 80 and or Span 80), it would have been obvious to one of ordinary skill in the art to also use lecithin in amount of between 0.1 and 3300 ppm (given product is treated in a solution of 1 to 10000 ppm concentration wherein 10-30% of the solution comprises lecithin - claims 3-4).

While Garcia-Mina et al. disclose a composition dissolved in an aqueous base and diluted with water, the reference does not explicitly disclose that the composition is dissolved in 30% to 60% vegetable oil.

Schur teaches a composition for impacting the surface of microbially perishable products comprising a microbiologically active substance and lecithin diluted in vegetable oil (C2/53-54, C6/L3-6, C9/L24-30,46-53).

Garcia-Mina et al. and Schur are combinable because they are concerned with the same field of endeavor, namely, stabilization of microbially perishable products. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to have used vegetable oil, as taught by Schur, to dilute the composition of Garcia-Mina et al. because doing so would amount to nothing more than the use of a known food grade dilutant for its intended use in a known environment to accomplish entirely expected results.

As fluidity and ease of application are variables that can be modified, among others, by adjusting the amount of vegetable oil base, the precise amount of vegetable oil base would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed amount of vegetable oil cannot be considered critical. Accordingly, it would have been obvious one of ordinary skill in the art at the time the invention to have adjusting by routine processing the amount of vegetable oil in the composition of modified Garcia-Mina et al. to obtain the desired fluidity and application efficiency.

Regarding **claims 40-41**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. does not disclose that the lecithins contain 30% to 60% lysolecithins. A skilled artisan would know that the hydrolyzed form of lecithin, lysolecithin, has superior emulsification properties to lecithin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced a portion, including between

30% and 60% of all of the lecithin, in the composition of Garcia-Mina et al. with lysolecithin for the purpose of making a more stable emulsion with the treatment agent ingredient.

Regarding **claim 42**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Since Garcia-Mina et al. disclose lecithin ([0019]), the limitations of this claim have been met.

Regarding **claim 43**, Garcia-Mina et al. disclose all of the claim limitations as set forth above and that the treatment agents and lecithin are formulated to be administered simultaneously ([0019]).

Regarding **claims 47 and 54**, Garcia-Mina et al. disclose a composition containing a treatment agent, i.e. eugenol, for fruits and vegetables and lecithin (Abstract, [0019]).

Specifically, Garcia-Mina et al. also disclose a composition that comprises 15% eugenol, 20% surface-active complex (i.e. lecithin - [0019]), and 25% water ([0035]).

While Garcia-Mina et al. disclose a composition dissolved in an aqueous base and diluted with water, the reference does not explicitly disclose that the composition is dissolved in 30% to 60% vegetable oil.

Schur teaches a composition for impacting the surface of microbially perishable products comprising a microbiologically active substance and lecithin diluted in vegetable oil (C2/53-54, C6/L3-6, C9/L24-30,46-53).

Garcia-Mina et al. and Schur are combinable because they are concerned with the same field of endeavor, namely, stabilization of microbially perishable products. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to have used vegetable oil, as taught by Schur, to dilute the composition of Garcia-Mina et al. because doing

so would amount to nothing more than the use of a known food grade dilutant for its intended use in a known environment to accomplish entirely expected results.

As fluidity and ease of application are variables that can be modified, among others, by adjusting the amount of vegetable oil base, the precise amount of vegetable oil base would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed amount of vegetable oil cannot be considered critical. Accordingly, it would have been obvious one of ordinary skill in the art at the time the invention to have adjusting by routine processing the amount of vegetable oil in the composition of modified Garcia-Mina et al. to obtain the desired fluidity and application efficiency.

Regarding **claim 48**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agents and lecithin are formulated in order to be administered simultaneously ([0019]).

Regarding **claims 56-57**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the ratio of lecithin to the treatment agent is about 1.3 (*see* 20% surface active complex (i.e. lecithin-[0019]) to 15% eugenol – [0035]).

Regarding **claim 58**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. does not disclose that the lecithin contains between 5% and 15% lysolecithin. A skilled artisan would know that the hydrolyzed form of lecithin, lysolecithin, has superior emulsification properties to lecithin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced a portion, or

all of the lecithin, in the composition of modified Garcia-Mina et al. with lysolecithin for the purpose of making a more stable emulsion with the treatment agent ingredient.

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Regarding **claim 59**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose applying the composition to fruits and vegetables (Abstract, [0032]).

Regarding **claim 60**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the composition is diluted in water to a dose between 1 and 10000 ppm ([0019], [0032]).

Regarding **claim 61**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the composition is diluted in water and applied at a temperature of from 45° to 50°C ([0032]).

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Regarding **claims 62-63**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the composition is applied by mean of showering or immersion ([0019]/L11-12). Garcia-Mina et al. also disclose use of the composition post-harvest ([0016/L37).

Regarding **claim 64**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. does not disclose that the application of the composition is carried out before harvesting the fruit or vegetable. Given that the composition is used to control post-harvest pathologies, it would have been obvious to a skilled artisan to have applied the composition to the fruit or vegetable at any time prior to distribution and achieve the same benefits.

Regarding **claim 66**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. While Schur teaches mixing lecithin and a microbiologically active substance (i.e. eugenol) in a vegetable oil base, the reference does not explicitly teach adding lecithin to the vegetable oil base followed by addition of the active substance. To switch the order of performing process steps, i.e. the order of the addition of the ingredients into the final composition, would be obvious absent any clear and convincing evidence and/or arguments to the contrary (MPEP 2144.04[R-1]). "Selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results."

Regarding **claim 67**, Garcia-Mina et al. disclose a method for controlling post-harvest pathology of fruits and vegetables (i.e. affliction of pathogenic agents and processes of chemical degeneration of the skin) comprising mixing a composition containing an active ingredient

selected from eugenol, terpineol, and geraniol and a surface active including lecithin (Abstract, [0001], [0016], [0019]) in an aqueous base (*see* [0035]/Formula 1 and [0042]/Formula 2).

Garcia-Mina does not disclose that the lecithin and treatment agents are mixed in an oil base or that the method is for preserving lecithins and/or derivatives thereof.

Schur teaches a composition for impacting the surface of microbially perishable products comprising a microbiologically active substance and lecithin diluted (i.e. mixed) in vegetable oil (C2/53-54, C6/L3-6, C9/L24-30,46-53).

Garcia-Mina et al. and Schur are combinable because they are concerned with the same field of endeavor, namely, stabilization of microbially perishable products. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to have mixed the treatment agent and lecithin in Garcia-Mina et al, with vegetable oil, as taught by Schur, because doing so would amount to nothing more than the use of a known food grade dilutant for its intended use in a known environment to accomplish entirely expected results.

The recitation that says the method is for preserving lecithins does confer patentability to the claim since statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product

patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Regarding **claim 68**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agent has fungicidal properties ([0002]/L8).

Regarding **claim 69**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agent is eugenol (Abstract, [0019]).

Regarding **claims 70-71**, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agent represents 40% by weight of the lecithin (*see* preparation of 1 kg. product where eugenol is 40% of the surface active substance – [0031]).

Response to Arguments

9. Applicant's arguments filed January 11, 2011 and February 7, 2011 have been fully considered but they are not persuasive.

Applicant notes that the "presently-claimed methods and compositions are further distinguished over the Garcia-Mina reference which requires additional active chemical treatments agents beyond eugenol." Applicant points out that "Garcia-Mina is specifically directed towards composition that include a second active agent, which can be thymol, cinnamaldehyde or a number of other ingredients, and Garcia-Mina further describes a treatment with a composition that includes relatively large amounts of active ingredients in addition to

eugenol" (as described at paragraph [0031] of Garcia-Mina). Applicant explains that the "claimed invention makes use of limited amounts of eugenol and provide eugenol in a specific corresponding range of amounts relative to lecithin amounts that are used." Applicant submits that the claimed combination of eugenol and lecithin "leads to a far improved inhibition of phytotoxicity and associated beneficial effects that are not described nor suggested by Garcia-Mina."

In this case, Garcia-Mina teaches a method for treating fruits and vegetables and the corresponding composition comprising a ratio of eugenol to lecithin substantially similar to that presently claimed. One of ordinary skill in the art would expect that the combination of eugenol and lecithin taught by Garcia-Mina would behave similarly to that of the presently claimed combination. Applicant has not demonstrated that the additional components taught by Garcia-Mina would impede the inhibition of phytotoxicity resulting from the combination of eugenol and lecithin.

Applicants submit that "the incorporation of additional ingredients recited in Garcia-Mina would materially change the characteristics of the present invention and would thus be excluded from the presently-claimed methods and compositions." Applicant explains that both thymol and cinnamaldehyde are known by those skilled in the art as phytotoxic agents. Therefore, Applicant argues that "the compounds of the present invention would necessarily exclude the additional active ingredients recited in Garcia-Mina because the incorporation of thymol and/or cinnamaldehyde into the compositions would be expected to increase their phytotoxicity and would thus materially change the characteristics of Applicant's invention."

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In this case, eugenol is also known to be phytotoxic to fruit and vegetables (Specification, page 2, lines 10-19). It is unclear how "other" active ingredients would contribute differently to phytotoxicity than eugenol. *Clarification is requested*.

While it is recognized that the phrase "consisting essentially of" narrows the scope of the claims to the specified ingredients and those which do not materially affect the basic and novel characteristics of the claimed invention, absent a clear indication of what the basic and novel characteristics are, "consisting essentially of" is construed as equivalent to "comprising".

Further, the burden is on the applicant to show that the additional ingredients in the prior art, would in fact be excluded from the claims and that such ingredients would materially change the characteristics of the applicant's invention, See MPEP 2111.03.

Here, Applicant claims a method "for reducing phytotoxicity" caused by the chemical treatment of a fruit or vegetable wherein the chemical treatment agent consists essentially of eugenol or salts thereof. Applicant has not shown that the additional components taught by Garcia-Mina would alter the basic and novel characteristics of applicant's claimed invention. Specifically, Applicants has not pointed out why the additional components should be excluded or why one of ordinary skill in the art wouldn't reasonably expect to get same results, i.e. reduced phytotoxicity, as Applicant has with the additional components of Garcia-Mina. Applicant has not shown why the additional components are undesirable in the present invention.

Additionally, Examiner notes that Garcia-Mina teaches the equivalency of using lecithin and Twen 80. Applicants have not shown that Twen 80 doesn't behave the same as lecithin in the present invention.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH GWARTNEY whose telephone number is (571)270-3874. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, D. Lawrence Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/ELIZABETH GWARTNEY/ Acting Examiner of Art Unit 1781